Title: VIRTUAL PROTOTYPING AND TESTING FOR MEDICAL DEVICE DEVELOPEMENT.
Applicant: Whirley and Chobotov
Serial No. 09/679,725 Filed: October 4, 2000
Our Docket No.: 24641-1070

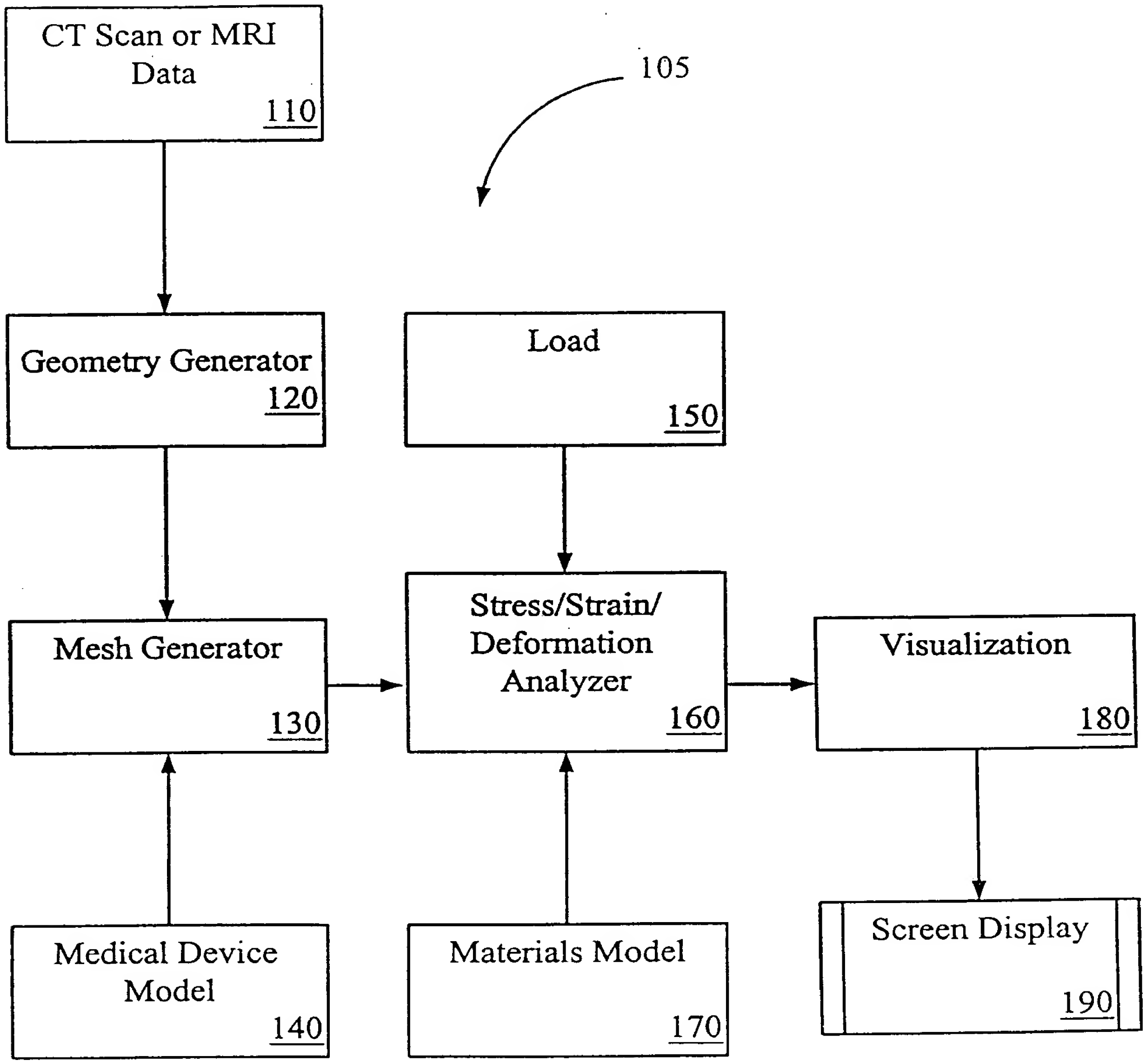

FIG. 1

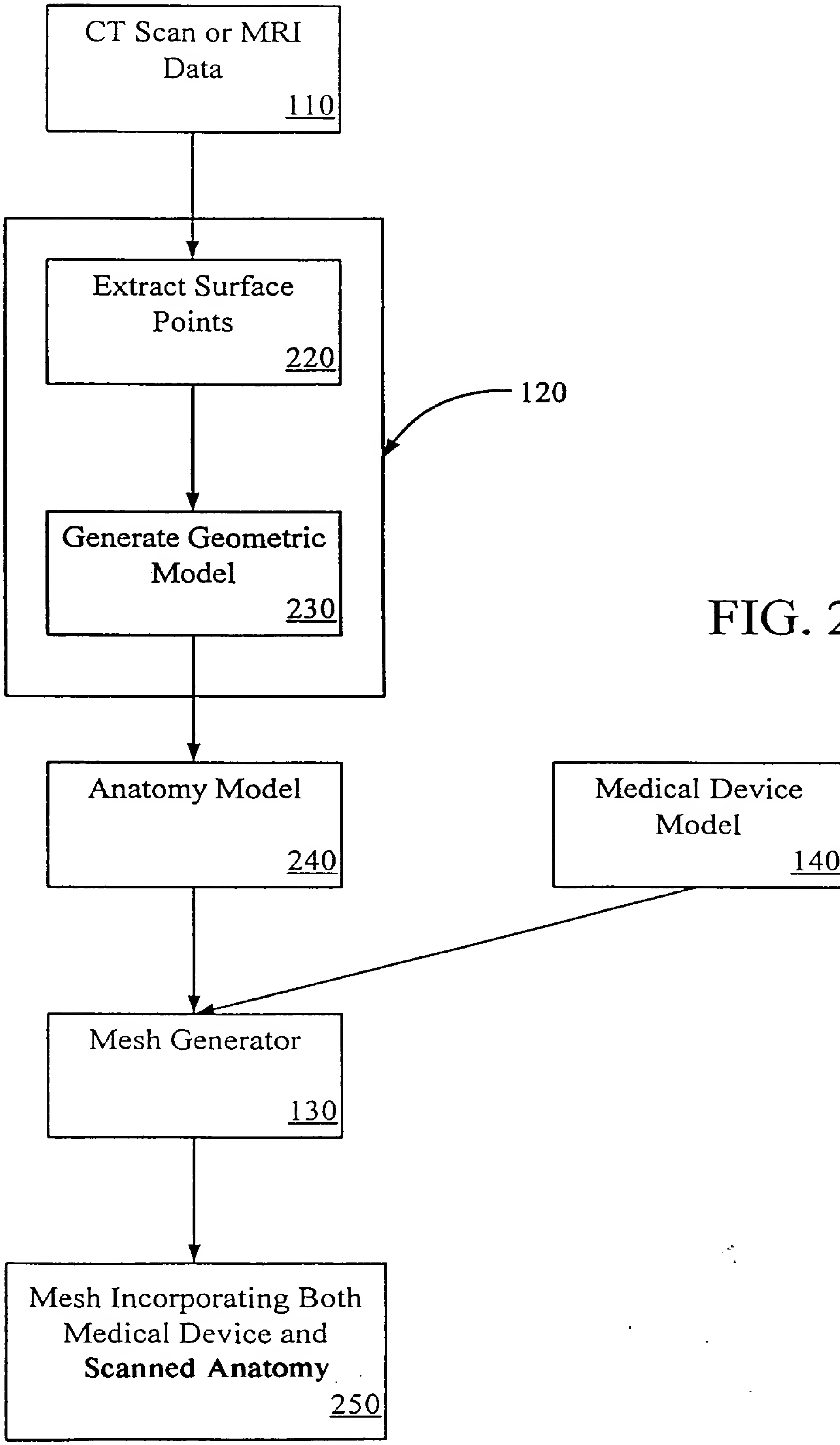
CT Scan or MRI Data
110
Extract Surface Points
220
120
Generate Geometric Model
230
Anatomy Model
240
Medical Device Model
140
Mesh Generator
130
Mesh Incorporating Both Medical Device and Scanned Anatomy
250

FIG. 2

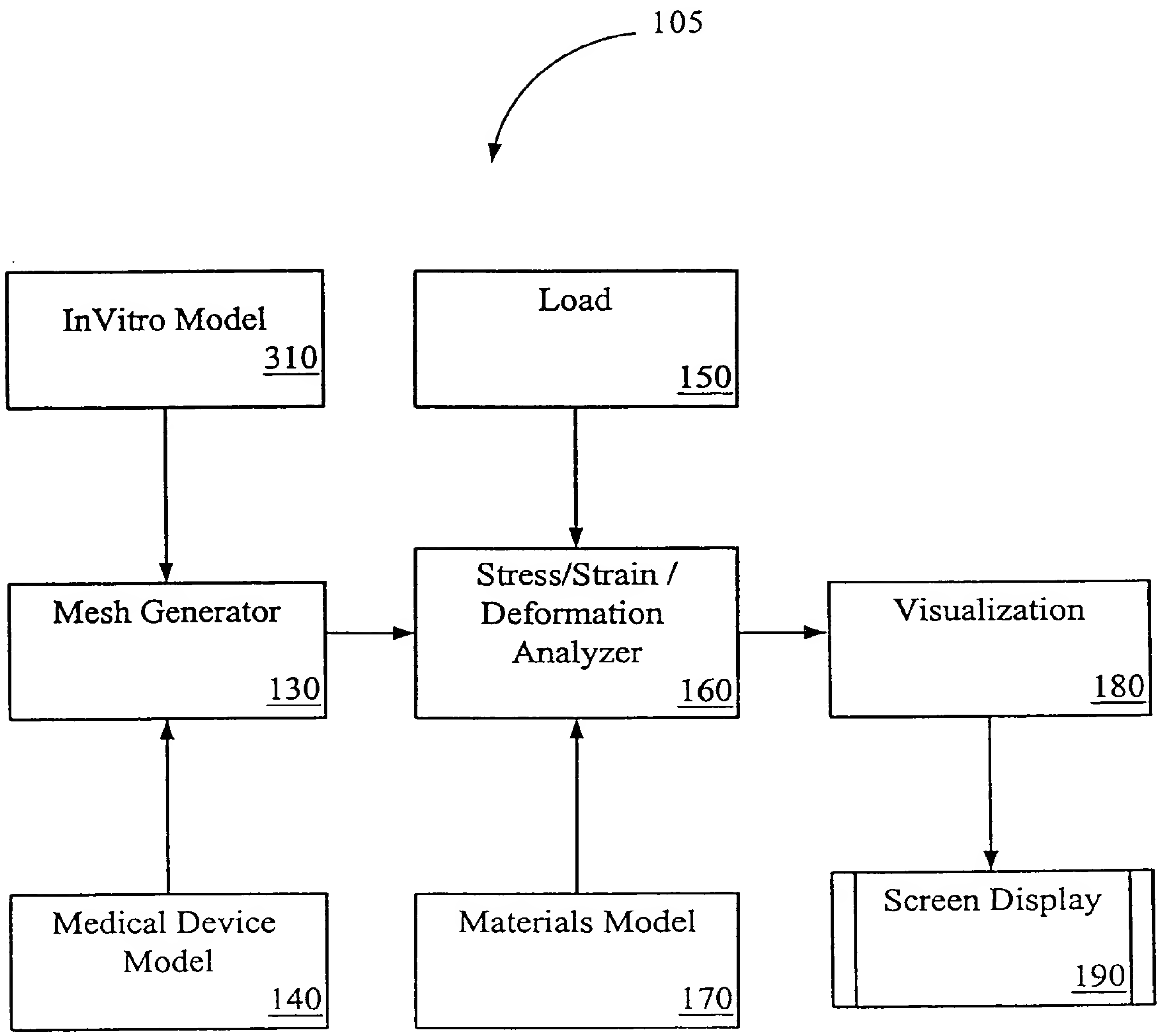
105
InVitro Model
310
Load
150
Mesh Generator
130
Stress/Strain / Deformation Analyzer
160
Visualization
180
Medical Device Model
140
Materials Model
170
Screen Display
190

FIG. 3

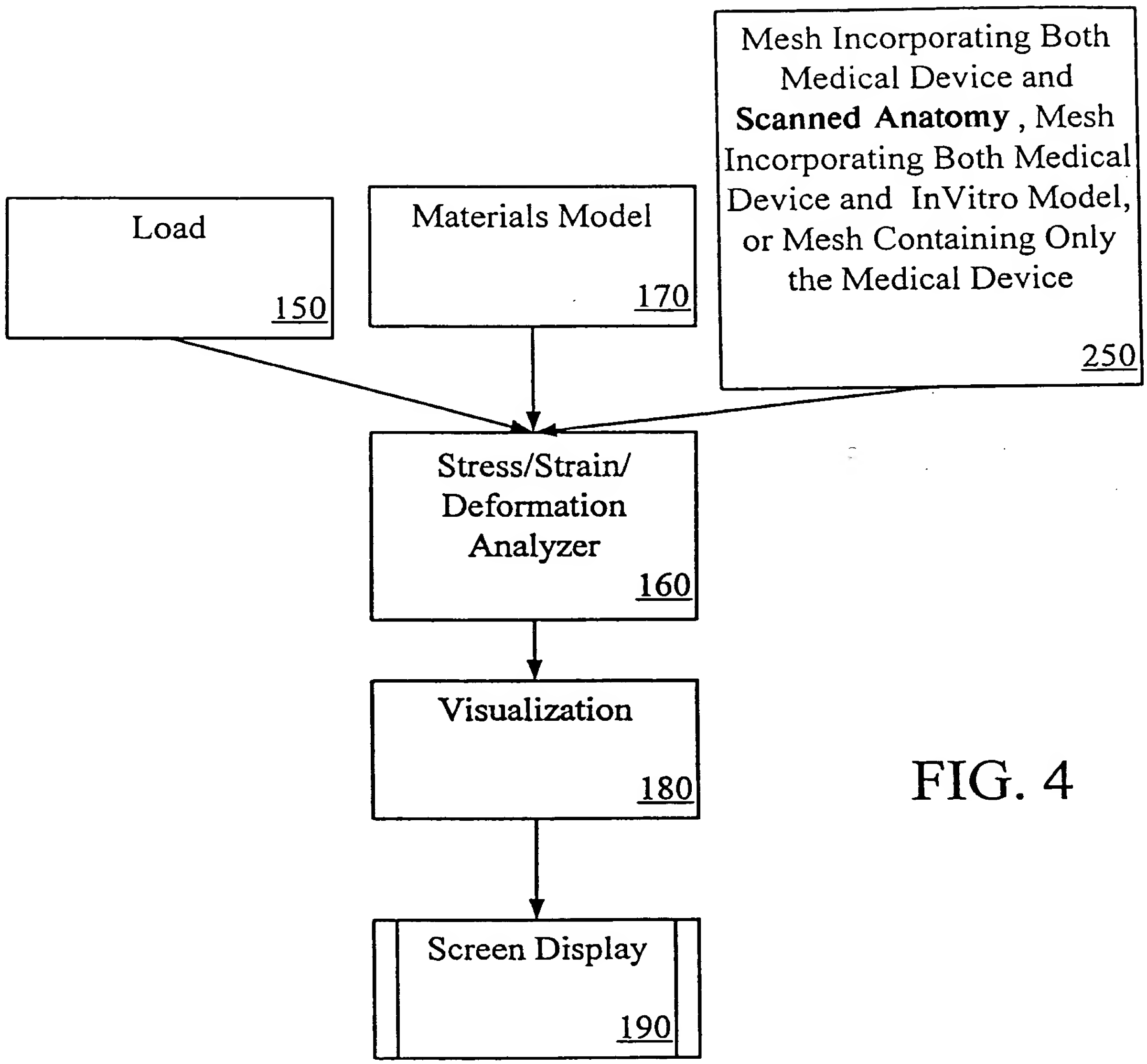
Load
150
Materials Model
170
Mesh Incorporating Both Medical Device and Scanned Anatomy, Mesh Incorporating Both Medical Device and InVitro Model, or Mesh Containing Only the Medical Device
250
Stress/Strain/ Deformation Analyzer
160
Visualization
180
Screen Display
190

FIG. 4

HELLER EHRMAN WHITE & MCAULIFFE LLP
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FIG. 5A

Line Command

```
c *** Slotted Tube Integrated Stent Design Simulation: istent.run ****
c
c -------------------- parameter settings -------------------
c
c .... inike=1 => make nike file; inike=0 => make dyna file
c .... imodel = 0 => full 3 segment model with interconnects
c            = 1 => 3-crown segment only
c            = 2 => 6-crown segment only
c            = 3 => 12-crown segment only
c .... isym = 0 => full 360 deg model
c          = 1 => symmetric model
c .... isim_mode:   type of simulation
c        = 1: => radial force to R_f = X% R_0, restoring stress mat'l
c        = 2: => flat plate force, restoring stress mat'l
c        = 3: => predelivery compression, loading stress mat'l
c        = 4: => initial expansion
c        = 5: => frequency analysis
c .... refine = X => add X elements via mseq in each direction
c                  of the cross section
c
parameter inike 1 ;
parameter imodel 0 ;
parameter isym 0 ;
parameter isim_mode 4 ;
parameter refine 2 ;
c
para Tighten [0.9];      c helps 'tighten' or stiffen spline
                         c  range (0.5,1) (probably should not change)
c
c -------------------- parameter settings -------------------
c
c ....  ======== design parameters ===============
c
c  Note:  Adjust specified OD for each segment considering the wall
c         thickness for that segment so that ID's match in a consistent
c         way for the tube blank from which they were cut.
c
c Upper segment ---  3 crowns
c Middle segment --  6 crowns
```

FIG. 5B

Line Command

```
c Lower segment --- 12 crowns (conical)
c
c Parameters for 3-crown segment
c
para
 RCyl3 [.5*2/25.4]
   dCIA3 [-.00]  c delta of center of inner arc for 3 crown segment (-:0)
   dCOA3 [0]     c delta of center of outer arc for 3 crown segment (0:+)
   CW3 [.007]    c Circumferential width of segments for 3 crowns
   RW3 [.005]    c Radial width for 3 crowns
   NRA3 [.0095]  c normal radius of smaller cylinders (arcs)
                 c  for 3 crowns
   Ht3 [0.224]   c distance from center of upper arcs
                 c  to center of lower arcs for 3 crowns
   NLegEl3 [12]; c number of elements along the leg

c
c Parameters for 6-crown segment
c
para
   RCyl6 [.5*2/25.4] c outside radius for 6 crown segment
   dCIA6 [0]     c delta of center of inner (smaller) arc for 6 crown
                    segment(-:0)
   dCOA6 [0.002] c delta of center of outer (larger) arc for 6 crown
                    segment (0:+)
   CW6 [.009]    c Circumferential width of segments for 6 crowns
   RW6 [.009]    c Radial width for 6 crowns
   NRA6 [.0105]  c normal radius of smaller cylinders (arcs)
                 c  for 6 crowns
   Ht6 [.115]    c distance from center of upper arcs
                 c  to center of lower arcs for 6 crowns
   NLegEl6 [12]; c number of elements along the leg

c
c Parameters for 12-crown segment
c
para
   dCIA12 [0]    c delta of center of inner arc for 12 crown segment (-:0)
```

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FIG. 5C

```
Line Command
   dCOA12 [0]        c delta of center of outer arc for 12 crown segment
                           (0:+)
   CW12 [.005]       c Circumferential width of segments for 12 crowns
   RW12 [.008]       c Radial width for 12 crowns
   NRA12 [.006]        c normal radius of smaller cylinders (arcs)
                  c  for 12 crowns
   Ht12 [.050]        c distance from center of upper arcs
                  c  to center of lower arcs for 12 crowns
                  c  (measured along the leg, not necessarily in
                  c  the z direction)
   c first outside radius for 12 crown segment (near other segments)
   RCyl12_1 [.5*2/25.4 - (.016-%RW12)]
   c second outside radius for 12 crown segment (bottom)
   RCYl12_2 [.5*1.4/25.4 - (.016-%RW12)]
c
   NLegEl12 [10];    c number of elements along the leg

c
c Interconnects
c

c
c Upper interconnects
c
para HIUp    [.02]    c height of interconnect
     FRUp   [.005]    c fillet radius for blend
     ICWUp  [.006]     c circumferential width
     IRWUp3 [.005]     c radial width at 3-crown end
     IRWUp6 [.006];    c radial width at 6-crown end

 c
 c S-interconnects
 c
 para SIVer [.01]    c vertical distance between upper or lower arc centers
                  c  also the distance from the vertical mid-line to
                  c  the first arc center
     SIHor [.010]  c horizontal distance between upper two or
                  c  lower two arc centers
     SIr   [.004]    c arc radius
```

FIG. 5D

Line Command

```
    SIrO [%SIr+%ICWUp/2]  c outer radius
    SIrI [%SIr-%ICWUp/2]; c inner radius

c
c Lower interconnects
c
para HILr    [.031]    c height of interconnect
    FRLr     [.010]    c fillet radius for blend
    ICWLr    [.007]    c circumferential width
    IRWLr6   [.005]    c radial width at 6-crown end
    IRWLr12  [.005];   c radial width at 12-crown end

c

c .... ======= design parameters =============
c
c .... set cylinder ID & OD for compression
c
if (%isim_mode.le.3) then
parameter ricompcyl
   [1.1*max(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)] ;
parameter rocompcyl
   [1.4*max(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)] ;
c
c .... set cylinder ID & OD for expansion
c
elseif (%isim_mode.eq.4) then
parameter rocompcyl
    [0.95*(min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)] ;
parameter ricompcyl
    [0.7*(min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)] ;
endif
c
c
c Materials assignments
c
parameter matst12 3 ;
parameter matst6  4 ;
parameter matst3  5 ;
```

FIG. 5E

Line Command

```
parameter mati126 6 ;
parameter mati63  7 ;
c
c
if (%isim_mode.eq.1) then
   echo *** Radial Force Simulation ***
elseif (%isim_mode.eq.2) then
   echo *** Flat Plate Force Simulation ***
elseif (%isim_mode.eq.3) then
   echo *** Predelivery Compression Simulation ***
elseif (%isim_mode.eq.4) then
   echo *** Initial Expansion Simulation ***
elseif (%isim_mode.eq.5) then
   echo *** Natural Frequency Analysis ***
else
   echo  !!! ERROR:  illegal isim_mode !!!
   interrupt
endif
c
c -------------------- analysis options --------------------
title  stent initial expansion simulation
c
c     *** DYNA3D Analysis Options ***
c
if (%inike.eq.0) then
 echo Making DYNA3D input file
 dyna3d
   dynaopts
   term 5.0e-5
   plti 1.e-6
   prti 5.0e-6
c
c .... DR options
c
  itrx 500
  tolrx 1.0e-2
  drdb
c
c .... thermal effects option - temp from load curve 1
```

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FIG. 5F

Line Command

```
c
 teo 1
c
 tssf 0.0
c
c print initial time step size
c
c prtflg 1
c
c .... turn off (0) or on (1) SAND database flag
c
 edsdf 0
c
 nrest 90000
  nrunr 95000 ;
c
c .... DYNA3D discrete nodes impacting surface - stent to cyl
c             * one side (180 deg) *
c
sid 1 dni
c sfif
c mfif
pnlts 1.0e-0
pnltm 1.0e-0
 ;
c
c .... DYNA3D discrete nodes impacting surface - stent to cyl
c             * opposite side *
c
c sid 2 dni
c sfif
c mfif
c pnlts 1.0e-4
c pnltm 1.0e-4
c  ;
c
c .... end DYNA3D commands
c
endif
```

FIG. 5G

Line Command

```
c
c
c    *** NIKE3D Analysis Options ***
c
if (%inike.eq.1) then
  echo Making NIKE3D input file . . .
  nike3d
  nikeopts
   nstep 5
   delt 0.2
   anal stat
c
c .... step tol of 1e-8 seems OK for predel compression
c
if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
   dctol -1.0e-8
elseif (%isim_mode.eq.3) then
   dctol -1.0e-6
endif
c
c .... max iterations per stiffness reform
c
   nibsr 20
c
c .... max stiffness reforms per step
c
   msrf 20 ;
c
c .... temperatures follow load curve 1
c    ** manually add tref=1.0 on matl 2 control card cols 26-35 **
c
   teo 1
if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
   iprt 1
elseif (%isim_mode.eq.3.or.%isim_mode.eq.4) then
   iprt 25
endif
   iplt 1
   nsbrr 1
```

FIG. 5H

Line Command

```
  stifcore 1
  bfgscore
  bwmo new
  echo  Bandwidth minimization ACTIVATED with "NEW" option
c
c  element constitutive data incore
c
  bfor 10
  sfor 10
  bef  11
c
c .... linear solver
c
 lsolver fissle
c
c .... solid element stent contact surface
c
sid 1 sv
c
if (%isim_mode.eq.1) then
c
c
 pnlt 1.0e-5
elseif (%isim_mode.eq.2) then
 pnlt 0.00001
elseif (%isim_mode.eq.3) then
c
c .... essential to adjust penalty
c
pnlt 1.0e+4
elseif (%isim_mode.eq.4) then
 pnlt 1.0e-5
c iaug 1 ;
endif
 ;
c
c .... slidesurface between interconnects and segments
c
sid 2 tied
```

FIG. 5I

Line Command

```
 ;
c
c .... NIKE3D shell geometric stiffness (HL only)
c
 segs 1 ;
c
c .... end NIKE3D section
c
endif
c
c .... symmetry planes
c
if (%isym.eq.1) then
c
c ....  Symmetric Model
c      theta=-60 and +60 symmetry to remove rigid body modes
c
c plane 1
c  0.0 0.0 0.0
c  [-sin(60)] [-cos(60)] 0.0
c    0.0005 symm ;
c plane 2
c  0.0 0.0 0.0
c  [-sin(60)] [cos(60)] 0.0
c    0.0005 symm ;
c
else
c
c .... symmetry planes to remove rigid body modes for full model
c
plane 1
  0.0  0.0  0.0
  1.0  0.0  0.0
   .0005 symm ;
plane 2
  0.0  0.0  0.0
  0.0  1.0  0.0
   .0005 symm ;
c plane 3
```

FIG. 5J

Line Command

```
c  0.0  0.0  0.0
c  0.0  0.0  TBD
c    .0005 symm ;
endif
c
c
if (%inike.eq.0) then
c
c .... Load Curves for DYNA3D  **ADD DR FLAG TO INPUT FILE **
c
if (%isim_mode.eq.1) then
c
c .... radial force
c
lcd 1
    0.000E+00 1.000E+00
    7.500E-03 2.250E+04
    1.000E-00 2.250E+04 ;
c   1.000E-02 3.000E+04
c   1.000E-00 3.000E+04 ;
elseif (%isim_mode.eq.2) then
c
c .... flat plate compression, lcd 1 not used (dummy definition)
c
quit
c
elseif (%isim_mode.eq.3) then
c
c .... predelivery compression strain
c
lcd 1
    0.000E+00 1.000E+00
    1.000E-02 2.008E+05
    1.000E-00 2.008E+05 ;
endif
c
c .... load curve #2 only used for flat plate compression
c
lcd 2
```

FIG. 5K

Line Command

```
   0.000E+00  0.000E+00
   1.000E+00  0.000e-00 ;
endif
c
if (%inike.eq.1) then
c
c .... ******** Load Curves for NIKE3D **********
c
if (%isim_mode.eq.1) then
c
c .... radial force
c
lcd 1
    0.000E+00 1.000E+00
    1.000E+00 2.000E+03 ;
elseif (%isim_mode.eq.2) then
c
c .... flat plate compression
c
lcd 1
    0.000E+00 1.000E+00
    1.000E+00 0.000E+00 ;
elseif (%isim_mode.eq.3) then
c
c .... predelivery compression strain
c
lcd 1
    0.000E+00 1.000E+00
    1.000E+00 2.008E+03 ;
elseif (%isim_mode.eq.4) then
c
c .... initial expansion strain
c
lcd 1
c .... thermal load (activate TEO above)
c    0.000E+00  1.000E+00
c    1.000E+00 -2.008E+04 ;
c .... prescribed displacement
    0.000E+00  0.000E+00
```

FIG. 5L

Line Command

```
    1.000E+00  1.000E-02 ;
endif
c
c -------------------------- stent parts -----------------
c
include  irss.tg
c
c -------------------------- stent materials -----------------
c
if (%inike.eq.1) then
      if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
         include istent.mats_nike_solid
         echo  model for radial force/flat plate analysis
      elseif (%isim_mode.eq.3) then
         include istent.mats_compress_nike_solid
         echo  model for predelivery compression strain
      elseif (%isim_mode.eq.4) then
         include istent.mats_compress_nike_solid
         echo  model for initial expansion strain
      endif
c
elseif (%inike.eq.0) then
      if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
         include istent.mats_dyna_solid
         echo  model for radial force/flat plate analysis
      elseif (%isim_mode.eq.3) then
         include istent.mats_compress_dyna_solid
         echo  model for predelivery compression strain
      elseif (%isim_mode.eq.4) then
         include istent.mats_compress_dyna_solid
         echo  model for initial expansion strain
      endif
endif
c
c .... cylindrical compression for radial force or predelivery compression
c
if (%isim_mode.eq.1.or.%isim_mode.eq.3.or.%isim_mode.eq.4) then
c
   if (%isym.eq.1) then
```

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FIG. 5M

```
Line Command
          include cylinder.parts_sym
       else
          include cylinder.parts
       endif
     c
     if (%inike.eq.1) then
       include cylinder.materials_nike
     elseif (%inike.eq.0) then
       include cylinder.materials_dyna
     endif
     endif
     c
     stp .01
     merge
     c
```

FIG. 6A

```
c ********** TPEG Inflatable Proximal Seal Simulation ******************
c                    (seal.run)
c                    March, 1999
c
c ------------------- parameter settings -------------------
c
c .... analytical model aorta geometric parameters
c      (distortion is 4-lobe)
c
parameter r_aorta [10.0/25.4] ;
parameter thk_aorta [1.0/25.4] ;
parameter amp_plaque [0.0/25.4] ;
c
parameter ro_aorta [%r_aorta+%thk_aorta] ;
c
c ....  -- TPEG Design Parameters --
c
parameter r_tpeg [10/25.4] ;
parameter r_ps [3/25.4] ;
parameter l_tpeg 2.0 ;
parameter l_flap 0.25 ;
c
parameter graft_wall_thick [6*0.0013] ;
parameter cuff_wall_thick  [3*0.0013] ;
parameter flap_wall_thick  [6*0.0013] ;
c
c
c .... Pressures and load curve assignments
c
parameter P_hemo 2.32 ;
parameter P_cuff 3.0 ;
c
parameter lc_hemo 1 ;
parameter lc_proxcuff 3 ;
c
c .... TPEG folding simulation parameters
c
parameter vel_fold 20.0 ;
parameter t_fold [0.25/%vel_fold] ;
parameter t_init 0.0e-3 ;
c
c
```

FIG. 6B

```
c -------------------- analysis options --------------------
title sc6.i Seal CT-Solid r_t=10mm r_ps=3mm  P_cuff=3.0 990428
c
c    *** DYNA3D Analysis Options ***
c
dyna3d
dynaopts
 term 6.5e-2
 plti 5.e-4
 prti 2.5e-2
c
c .... DR options
c
itrx 500
c
c .... increase DR tol to prevent convergence after compression before expansion
c
c tolrx 1.0e-6
tolrx 1.0e-12
drdb
c
 tssf 0.9
c
c .... turn off (0) or on (1) SAND database flag
c
  edsdf 0
c
  nrest 90000
  nrunr  5000 ;
c
c .... symmetry planes on xz and yz planes
c
plane 1
  0.0 0.0 0.0
  1.0 0.0 0.0    0.001    symm ;
plane 2
  0.0 0.0 0.0
  0.0 1.0 0.0    0.001    symm ;
c
c .... DYNA3D slidesurface:  +x folder cylinder
c
sid 1 sv
```

FIG. 6C

```
pnlts 1.0
pnltm 1.0
pen
 ;
c
c .... DYNA3D slidesurface:  -x folder cylinder
c
sid 2 sv
pnlts 1.0
pnltm 1.0
pen
 ;
c
c
c .... DYNA3D slidesurface:  +y folder cylinder
c
sid 3 sv
pnlts 1.0
pnltm 1.0
pen
 ;
c
c .... DYNA3D slidesurface:  -y folder cylinder
c
sid 4 sv
pnlts 1.0
pnltm 1.0
pen
 ;
c
c .... DYNA3D tpeg to aorta (aorta is master)
c
sid 5 sv
c
c .... solid element aorta
c
pnlts 0.1
pnltm 0.1
c
c .... shell element aorta
c
c pnlts 1.0
```

FIG. 6D

```
c pnltm 1.0
pen
 ;
c
c .... load curve:  hemodynamics  **** ADD DR FLAG TO INPUT FILE ****
c
lcd 1
  0.000E+00               0.000E+00
  [%t_init+2*%t_fold+1.0e-3]  0.000e+00
  [%t_init+2*%t_fold+2.0e-3]  %P_hemo
  1.000E+00               %P_hemo ;
c
c .... load curve:  channel !! NOT USED !! **** ADD DR FLAG TO INPUT FILE ****
c
lcd 2
  0.000E+00 0.000E+00
  [%t_init+2*%t_fold+1.0e-3]  0.000e+00
  [%t_init+2*%t_fold+2.0e-3]  0.000e-00
  1.000E+00               0.000e-00 ;
c
c .... load curve: proximal cuff  **** ADD DR FLAG TO INPUT FILE ****
c
lcd 3
  0.000E+00 0.000E+00
  [%t_init+2*%t_fold+1.0e-3]  0.000e+00
  [%t_init+2*%t_fold+2.0e-3]  %P_cuff
  1.000E+00               %P_cuff ;
c
c .... load curve for +x folder cylinder motion/velocity
c
lcd 4
  0.000E+00                 0.000E+00
  %t_init                 0.000E+00
  [%t_init+1.0E-04]            [-%vel_fold]
  [%t_init+%t_fold]            [-%vel_fold]
  [%t_init+%t_fold+1.0e-3]       0.000E+00
  [%t_init+2*%t_fold+1.0e-3]     0.000e+00
  [%t_init+2*%t_fold+2.0e-3]     [2.0*%vel_fold]
  [%t_init+3*%t_fold+2.0e-3]     [2.0*%vel_fold]
  [%t_init+3*%t_fold+3.0e-3]     0.000e+00
  1.000E+00          0.000E+00 ;
c
```

FIG. 6E

```
c .... load curve for -x folder cylinder motion
c
lcd 5
 0.000E+00                  0.000E+00
 %t_init                    0.000E+00
 [%t_init+1.000E-04]        [ %vel_fold]
 [%t_init+%t_fold]          [ %vel_fold]
 [%t_init+%t_fold+1.0e-3]   0.000E+00
 [%t_init+2*%t_fold+1.0e-3]    0.000e+00
 [%t_init+2*%t_fold+2.0e-3]    [-2.0*%vel_fold]
 [%t_init+3*%t_fold+2.0e-3]    [-2.0*%vel_fold]
 [%t_init+3*%t_fold+3.0e-3]    0.000e+00
 1.000E+00                  0.000E+00 ;
c
c .... load curve for +y folder cylinder motion
c
lcd 6
 0.000E+00                  0.000E+00
 %t_init                    0.000E+00
 [%t_init+1.000E-04]        [-%vel_fold]
 [%t_init+%t_fold]          [-%vel_fold]
 [%t_init+%t_fold+1.0e-3]   0.000E+00
 [%t_init+2*%t_fold+1.0e-3]    0.000e+00
 [%t_init+2*%t_fold+2.0e-3]    [2.0*%vel_fold]
 [%t_init+3*%t_fold+2.0e-3]    [2.0*%vel_fold]
 [%t_init+3*%t_fold+3.0e-3]    0.000e+00
 1.000E+00                  0.000E+00 ;
c
c .... load curve for -y folder cylinder velocity
c
lcd 7
 0.000E+00                  0.000E+00
 %t_init                    0.000E+00
 [%t_init+1.000E-04]        [ %vel_fold]
 [%t_init+%t_fold]          [ %vel_fold]
 [%t_init+%t_fold+1.0e-3]   0.000E+00
 [%t_init+2*%t_fold+1.0e-3]    0.000e+00
 [%t_init+2*%t_fold+2.0e-3]    [-2.0*%vel_fold]
 [%t_init+3*%t_fold+2.0e-3]    [-2.0*%vel_fold]
 [%t_init+3*%t_fold+3.0e-3]    0.000e+00
 1.000E+00                  0.000E+00 ;
c
```

FIG. 6F

```
c ------------------------- parts and materials -----------------
c
c
c .... get CT-data meshed aorta; convert cm to inches
c
csca [1./2.54]
include tpeg.part_ct_aorta3
c
csca 1.0
c
c .... option for analytical aorta model
c
c include tpeg.part_eq_aorta
c
include tpeg.part_cuff1
include tpeg.part_folder2
c
include tpeg.materials_dyna
c
c .... use negative tols to prevent aorta nodes merging w/ folder cylinder
c      nodes if they coincidently become adjacent
c
c .... merge nodes within CT aorta part using rather loose tolerance
c
bptol 1 1 0.01
bptol 1 3 -1.0
bptol 1 4 -1.0
bptol 1 5 -1.0
bptol 1 6 -1.0
tp .001
c
```

FIG. 7A

```
c
c              tpeg.part_ct_aorta3
c               April 15, 1999
c
c ------- Aortic Model for Inflatable TPEG Model ---------
c          Derived from Patient CT Data
c          Outer surface constructed with 0.52 mm offset from inner
c
c .... this is an aortic mesh file which surrounds the neck of the
c      3-D AAA reconstruction with solid elements.
c
c      This file uses TrueGrid planes, oriented by eye using trial
c      and error graphically, to determine an orthonormal section.
c      Trick there is to adjust surface until walls of proximal neck section
c      are parallel to global z axis.  Use rz to rotate screen to find values,
c      then use in surface transformation to position CT data for meshing.
c
c .... import IGES file containing surface data from CT scan
c
iges solid1.igs 1 1 mx -18.54 my -16.8    ry 24 rx 22 mz  4.8;
c
c .... inner surface
c
sd 17 sds 9 12;
c
c .... outer surface
c
sd 18 sds 15 16 ;
c
sd 201 plan
     0. 0. 1.5
     0  0  1
sd 202 plan
     0. 0. 2.5
     0  0  1
sd 203 plan
     0. 0. -2.3
     0  0  1
sd 204 plan
     0. 0. 3.3
     0  0  1
sd 301 cy 0 0 0 0 0 1 1.35
```

FIG. 7B

```
sd 401 plan
     0. 0. 0.
     0. 1. 0.
c
c .... adjust mz to position part at cuff on Z-axis;
c        cuff may be z=[2,2.15]
cylinder
 1 2;
1 2 3;
1 2 3 4 ;
c
1.0 1.25
0 180.0 360.0
-2.3 1.5 2.5 3.3
c
mseq i 2
mseq j 29 29
mseq k 20 5 5
c
c .... project top and bottom ends of aorta segment onto orthonormal planes
c
sfi ; ; -2;  sd 201
sfi ; ; -3;  sd 202
c
c .... project top of upper neck segment onto orthonormal plane
c
sfi ; ; -4;  sd 204
c
c .... project bottom of lower neck segment onto orthonormal plane
c     after radially expanding bottom ring by delta-r=2.0
mbi -1; ; -1; x 2.0
mbi -2; ; -1; x 2.0
sfi ; ; -1;  sd 203
c
c .... project inner cylinder surface onto aorta luminal surface
c
sfi -1; 1 3; 2 3; sd 17
sfi -1; 1 3; 3 4; sd 17
sfi -1; 1 3; 1 2; sd 17
c
c .... project outer cylinder onto aorta outer wall surface
c
```

FIG. 7C

```
sfi -2; 1 3; 2 3; sd 18
sfi -2; 1 3; 3 4; sd 18
sfi -2; 1 3; 1 2; sd 18
c
c .... project theta=0/360 seam onto a plane to facilitate merging
c
sfi 1 2; -1; ;  sd 401
sfi 1 2; -3; ;  sd 401
c
c
c ... --- slidesurface definition with TPEG body ---
c
orpt + 0. 0. 3.0
sii  -1; 1 3; 3 4;  5 m
c
c .... +y hemicylinder is material 11; -y is mat 12
c
mti ; 1 2; 2 4 ;  11
mti ; 2 3; 2 4;  12
c
c .... rigid material for aneurysm sac
c
mti ; 1 3; 1 2;  13
c
c .... Boundary Conditions
c      * fix proximal end only in z
c
bi ; ; -4;  dz 1 ;
c
c .... adjust mz to position aorta at cuff on Z-axis;
c         cuff may be z=[2,2.15]
 lct 1
    mz  [1.01*2.54] mx 0.7; ;
 lrep 1 ;
endpart
c
```

FIG. 8A

```
c ****** Slotted Tube Integrated Stent Design Simulation *******
c              (istent.run)
c       Stent design analysis & CT-Anatomy simulation
c
c ------------------- parameter settings ------------------
c
c .... inike=1 => make nike file; inike=0 => make dyna file
c .... imodel = 0 => full 3 segment model with interconnects
c           = 1 => 3-crown segment only
c           = 2 => 6-crown segment only
c           = 3 => 12-crown segment only
c .... isym = 0 => full 360 deg model
c         = 1 => symmetric model
c .... isim_mode:   type of simulation
c        = 1: => radial force to R_f = 80% R_0, restoring stress mat'l
c        = 2: => flat plate force, restoring stress mat'l
c        = 3: => predelivery compression to 12 F, loading stress mat'l
c        = 4: => initial expansion
c        = 5: => frequency analysis
c        = 6: => anatomy deployment
c .... refine = X => add X elements via mseq in each direction
c              of the cross section
c
c  !!! warning - only 1st 8 characters of variable unique !!!!
c
parameter inike 1 ;
parameter imodel 2 ;
parameter isym 0 ;
parameter isim_mode 6 ;
parameter refine 1 ;
c
para Tighten [0.9];      c helps 'tighten' or stiffen spline
                 c   range (0.5,1) (probably should not change)
c
c ------------------- parameter settings ------------------
c
c ....  ======== design parameters ===============
c
c  Note:  Adjust specified OD for each segment considering the wall thickness
c        for that segment so that ID's match in a consistent way for the
c        tube blank from which they were cut.
c
c Upper segment ---  3 crowns
c Middle segment --  6 crowns
c Lower segment --- 12 crowns (could be conical)
c
c Parameters for 3-crown segment
c
para
```

FIG. 8B

```
 RCyl3 [29*0.5/25.4]
   dCIA3 [-.00]  c delta of center of inner arc for 3 crown segment (-:0)
   dCOA3 [0]     c delta of center of outer arc for 3 crown segment (0:+)
   CW3 [.020]    c Circumferential width of segments for 3 crowns
   RW3 [.018]    c Radial width for 3 crowns
   NRA3 [.0195]  c normal radius of smaller cylinders (arcs)
              c  for 3 crowns
   Ht3 [1.048]   c distance from center of upper arcs
              c  to center of lower arcs for 3 crowns
   NLegEl3 [12]; c number of elements along the leg
c
c Parameters for 6-crown segment
c
para
   RCyl6 [29*0.5/25.4]  c outside radius for 6 crown segment
   dCIA6 [0]     c delta of center of inner (smaller) arc for 6 crown segment (-:0)
   dCOA6 [0.005]  c delta of center of outer (larger) arc for 6 crown segment (0:+)
   CW6 [.020]    c Circumferential width of segments for 6 crowns
   RW6 [.018]    c Radial width for 6 crowns
   NRA6 [.0195]  c normal radius of smaller cylinders (arcs)
              c  for 6 crowns
   Ht6 [.310]    c distance from center of upper arcs
              c  to center of lower arcs for 6 crowns
   NLegEl6 [12]; c number of elements along the leg
c
c Parameters for 12-crown segment
c
para
   dCIA12 [0]       c delta of center of inner arc for 12 crown segment (-:0)
   dCOA12 [0]        c delta of center of outer arc for 12 crown segment (0:+)
   CW12 [.008]       c Circumferential width of segments for 12 crowns
   RW12 [.008]       c Radial width for 12 crowns
   NRA12 [.006]        c normal radius of smaller cylinders (arcs)
                 c  for 12 crowns
   Ht12 [.164]       c distance from center of upper arcs
                 c  to center of lower arcs for 12 crowns
                 c  (measured along the leg, not necessarily in
                 c  the z direction)
   c first outside radius for 12 crown segment (near other segments)
   RCyl12_1 [22*0.5/25.4]
   c second outside radius for 12 crown segment (bottom)
   RCYl12_2 [20*0.5/25.4]
c
   NLegEl12 [10];    c number of elements along the leg
c
c Interconnects
c
c Upper interconnects
c
```

FIG. 8C

```
para
c   HIUp   [.10]    c height of interconnect
    HIUp   [.20]    c height of interconnect
    FRUp   [.016]   c fillet radius for blend
    ICWUp  [.010]   c circumferential width
    IRWUp3 [.016]   c radial width at 3-crown end
    IRWUp6 [.016];  c radial width at 6-crown end
c
c S-interconnects
c
para
c   SIVer [.03]    c vertical distance between upper or lower arc centers
    SIVer [.06]    c vertical distance between upper or lower arc centers
                   c also the distance from the vertical mid-line to
                   c the first arc center
    SIHor [.0125]  c horizontal distance between upper two or
                   c lower two arc centers
    SIr  [.008]    c arc radius
    SIrO [%SIr+%ICWUp/2]  c outer radius
    SIrI [%SIr-%ICWUp/2]; c inner radius
c
c Lower interconnects
para
c   HILr   [.071]   c height of interconnect
    HILr   [.142]   c height of interconnect
    FRLr   [.016]   c fillet radius for blend
    ICWLr  [.016]   c circumferential width
    IRWLr6  [.005]  c radial width at 6-crown end
    IRWLr12 [.005]; c radial width at 12-crown end
c
c .... ========= design parameters ===============
c
c .... set cylinder ID & OD for compression
c
if (%isim_mode.le.3.or.%isim_mode.eq.6) then
parameter ricompcyl [1.1*max(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)] ;
parameter rocompcyl [1.4*max(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)] ;
c
c .... set cylinder ID & OD for expansion
c
elseif (%isim_mode.eq.4) then
parameter rocompcyl [0.95*(min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)] ;
parameter ricompcyl [0.7* (min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)] ;
endif
c
c Materials assignments
c
parameter matst12 3 ;
parameter matst6  4 ;
```

FIG. 8D

```
parameter matst3  5 ;
parameter mati126 6 ;
parameter mati63  7 ;
c
if (%isim_mode.eq.1) then
   echo *** Radial Force Simulation ***
elseif (%isim_mode.eq.2) then
   echo *** Flat Plate Force Simulation ***
elseif (%isim_mode.eq.3) then
   echo *** Predelivery Compression Simulation ***
elseif (%isim_mode.eq.4) then
   echo *** Initial Expansion Simulation ***
elseif (%isim_mode.eq.5) then
   echo *** Natural Frequency Analysis ***
elseif (%isim_mode.eq.6) then
   echo *** Anatomy Deployment Simulation***
else
   echo  !!! ERROR:  illegal isim_mode !!!
   interrupt
endif
c
c -------------------- analysis options ------------------
title human-size stent anatomy deployment
c
c    *** DYNA3D Analysis Options ***
c
if (%inike.eq.0) then
 echo Making DYNA3D input file
 dyna3d
  dynaopts
  term 2.0e-4
  plti 1.e-4
  prti 5.0e-6
c
c .... DR options
c
c itrx 500
c tolrx 1.0e-6
c drdb
c
c .... thermal effects option - temp from load curve 1
c
if (%isim_mode.ne.5)  then
 teo 1
endif
c
 tssf 0.0
c
c print initial time step size
```

FIG. 8E

```
c
c prtflg 1
c
c .... turn off (0) or on (1) SAND database flag
c
 edsdf 0
c
 nrest 90000
  nrunr 95000 ;
c
c .... DYNA3D stent to compression cyl
c
sid 1 dni
c sfif
c mfif
pnlts 1.0e-0
pnltm 1.0e-0
 ;
c
c .... DYNA3D tied interface to interconnects if multisegment
c
if (%imodel.eq.0) then
sid 2 tied
 ;
endif
c
c .... end DYNA3D commands
c
endif
c
c    *** NIKE3D Analysis Options ***
c
if (%inike.eq.1) then
 echo Making NIKE3D input file . . .
 nike3d
 nikeopts
c
c .... temperatures follow load curve 1
c    ** manually add tref=1.0 on matl 2 control card cols 26-35 **
c
  teo 1
c
if (%isim_mode.eq.5) then
  anal dyn
  neig 20
  shift 69
  iplt 1
  nsbrr 1
  stifcore 1
```

FIG. 8F

```
  bfgscore
  bwmo new
c
c  element constitutive data incore
c
  bfor 10
  sfor 10
  bef  11
c
c .... linear solver
c
  lsolver fissle
c
elseif (%isim_mode.ne.5) then
c
c .... time step analysis
c
  nstep 100
  delt 0.0100
  anal stat
c
c .... step tol of 1e-2 is OK for predel compression
c
if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
  dctol -1.0e-3
elseif (%isim_mode.eq.3) then
  dctol -1.0e-2
endif
c
c .... max iterations per stiffness reform
c
  nibsr 20
c
c .... max stiffness reforms per step
c
  msrf 20 ;
if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
  iprt 1
elseif (%isim_mode.eq.3.or.%isim_mode.eq.4) then
  iprt 25
endif
  iplt 1
  nsbrr 1
  stifcore 1
  bfgscore
  bwmo new
  echo  Bandwidth minimization ACTIVATED with "NEW" option
c
c  element constitutive data incore
```

FIG. 8G

```
c
  bfor 10
  sfor 10
  bef  11
c
c .... linear solver
c
 lsolver fissle
c
c .... solid element stent contact surface
c
sid 1 sv
c
if (%isim_mode.eq.1) then
c
c .... below changed for sharp-edge laser-cut stent
c
  pnlt 1.0e-3
elseif (%isim_mode.eq.2) then
 pnlt 0.01
elseif (%isim_mode.eq.3) then
c
c .... essential to cut penalty for laser-cut stent predel compression
c
pnlt 0.001
elseif (%isim_mode.eq.4) then
  pnlt 1.0e-3
c iaug 1 ;
endif
 ;
c
c .... end block for time step only analysis
c
endif
c
c .... slidesurface between interconnects and segments
c
sid 2 tied
  ;
c
c .... slidesurface between stent and aortic wall
c
if (%isim_mode.eq.6) then
echo *** Add activation time of 0.5 to slidesurface 2 ***
sid 3 sv
;
endif
c
c .... NIKE3D shell geometric stiffness (HL only)
```

FIG. 8H

```
c
  segs 1 ;
c
c .... end NIKE3D section
c
endif
c
c .... symmetry planes (omit for freq analysis)
c
if (%isim_mode.ne.5) then
if (%isym.eq.1) then
c
c ....  Symmetric Model
c
c plane 1
c  0.0 0.0 0.0
c  [-sin(60)] [-cos(60)] 0.0
c    0.0005 symm ;
c plane 2
c  0.0 0.0 0.0
c  [-sin(60)] [cos(60)] 0.0
c    0.0005 symm ;
c
else
c
c .... symmetry planes to remove rigid body modes for full model
c
plane 1
  0.0  0.0  0.0
  1.0  0.0  0.0
    .0005 symm ;
plane 2
  0.0  0.0  0.0
  0.0  1.0  0.0
    .0005 symm ;
endif
endif
c
c
if (%inike.eq.0) then
c
c .... Load Curves for DYNA3D  **** ADD DR FLAG TO INPUT FILE ****
c
if (%isim_mode.eq.1) then
c
c .... radial force
c
lcd 1
    0.000E+00 1.000E+00
```

FIG. 8I

```
    7.500E-03 2.250E+02
    1.000E-00 2.250E+02 ;
elseif (%isim_mode.eq.2) then
c
c .... flat plate compression, lcd 1 not used (dummy definition)
c
echo !!! Flat plate not implemented for DYNA3D !!!
quit
c
elseif (%isim_mode.eq.3) then
c
c .... predelivery compression strain - 0.87 in. dia compressed to 12F
c       [check x-displ of stent center node to verify]
c
lcd 1
    0.000E+00 1.000E+00
    1.000E-02 1.008E+03
    1.000E-00 1.008E+03 ;
elseif (%isim_mode.eq.6) then
c
c .... anatomy deployment
c      (LC from radial comp)
c
lcd 1
    0.000E+00 1.000E+00
    7.500E-04 1.000E+03
    9.000E-04 1.000E+03
    1.500E-03 1.000E+00
    1.000E-00 1.000E+00 ;
endif
c
c .... load curve #2 only used for flat plate compression
c
lcd 2
   0.000E+00  0.000E+00
   1.000E+00  0.000e-00 ;
endif
c
if (%inike.eq.1) then
c
c .... ******** Load Curves for NIKE3D **********
c
if (%isim_mode.eq.1) then
c
c .... radial force
c
lcd 1
    0.000E+00 1.000E+00
    1.000E+00 3.000E+02 ;
```

FIG. 8J

```
elseif (%isim_mode.eq.2) then
c
c .... flat plate compression, lcd 1 not used (dummy definition)
c
lcd 1
    0.000E+00 1.000E+00
    1.000E+00 0.000E+00 ;
elseif (%isim_mode.eq.3) then
c
c .... predelivery compression strain - 0.87 in. dia compressed to 12F
c       [check x-displ of stent center node to verify]
c
lcd 1
    0.000E+00 1.000E+00
    1.000E+00 1.008E+03 ;
elseif (%isim_mode.eq.4) then
c
c .... initial expansion strain - 4/5 mm OD to 15/27 mm OD
c       [check x-displ of stent center node to verify]
c
lcd 1
c .... thermal load (activate TEO above)
    0.000E+00  1.000E+00
    1.000E+00 -1.008E+03 ;
c .... prescribed displacement
c   0.000E+00  0.000E+00
c   1.000E+00  1.000E-01 ;
c
elseif (%isim_mode.eq.5) then
c
c .... must define load curve since TEO active even if unused for freq
c
c .... initial expansion strain - 4/5 mm OD to 15/27 mm OD
c       [check x-displ of stent center node to verify]
c
lcd 1
c .... thermal load (activate TEO above)
    0.000E+00  1.000E+00
    1.000E+00 -1.008E+03 ;
elseif (%isim_mode.eq.6) then
c
c .... anatomy deployment - 0.87 in. dia compressed to 12F
c
lcd 1
    0.000E+00 1.000E+00
    0.500E+00 5.000E+02
    1.000E+00 1.000E+00 ;
endif
endif
```

FIG. 8K

```
c
c -------------------------- stent parts -----------------
c
include  irss.tg
c
c -------------------------- anatomy parts -----------------
c
if (%isim_mode.eq.6) then
c
c .... convert anatomy data from cm to inch units
c
control
csca [1./2.54]
c
c .... import meshed anatomy data for stent deployment
c        (this is an aortic stent)
c
include tpeg.part_ct_aorta3
csca 1.0
merge
if (%inike.eq.1) then
c
c .... set material properties for aortic wall
c
include aorta.materials_nike
endif
endif
c
c -------------------------- stent materials -----------------
c
if (%inike.eq.1) then
       if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
          include istent.mats_nike_solid
          echo  NiTi model for radial force/flat plate analysis
       elseif (%isim_mode.eq.3) then
          include istent.mats_compress_nike_solid
          echo  NiTi model for predelivery compression strain
       elseif (%isim_mode.eq.4) then
          include istent.mats_compress_nike_solid
          echo  NiTi model for initial expansion strain
       elseif (%isim_mode.eq.5) then
          include istent.mats_nike_freq_solid
          echo  NiTi model for frequency analysis
       elseif (%isim_mode.eq.6) then
          include istent.mats_nike_solid
          echo  NiTi model for anatomy deployment
       endif
c
elseif (%inike.eq.0) then
```

FIG. 8L

```
      if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
         include istent.mats_dyna_solid
         echo  NiTi model for radial force/flat plate analysis
      elseif (%isim_mode.eq.3) then
         include istent.mats_compress_dyna_solid
         echo  NiTi model for predelivery compression strain
      elseif (%isim_mode.eq.4) then
         include istent.mats_compress_dyna_solid
         echo  NiTi model for initial expansion strain
      elseif (%isim_mode.eq.6) then
         include istent.mats_compress_dyna_solid
         echo  NiTi model for anatomy deployment
      endif
endif
c
c .... cylindrical compression for radial force or predelivery compression
c
if (%isim_mode.eq.1.or.%isim_mode.eq.3.or.%isim_mode.eq.4.or.%isim_mode.eq.6) then
c
   if (%isym.eq.1) then
      include cylinder.parts_sym
   else
      include cylinder.parts
   endif
   endif
c
if (%inike.eq.1) then
  include cylinder.materials_nike
elseif (%inike.eq.0) then
  include cylinder.materials_dyna
endif
c
stp .0001
c
c .... Constrain stent node(s) in z-direction for time-hist analysis
c
if (%isim_mode.ne.5) then
merge
c
c .... nset for 3-segment model
c nset zconstr = 1 8149 8687 9215 9747  ;
c echo  ** Bottom 12-crown node list Constrained in Z-translation **
c
c .... nset for 6-crown only
echo  ** Bottom 6-crown node list constrained in z-dir **
nset zconstr = 1 43 97 151 448  ;
b nset zconstr dz 1 ;
endif
c
```

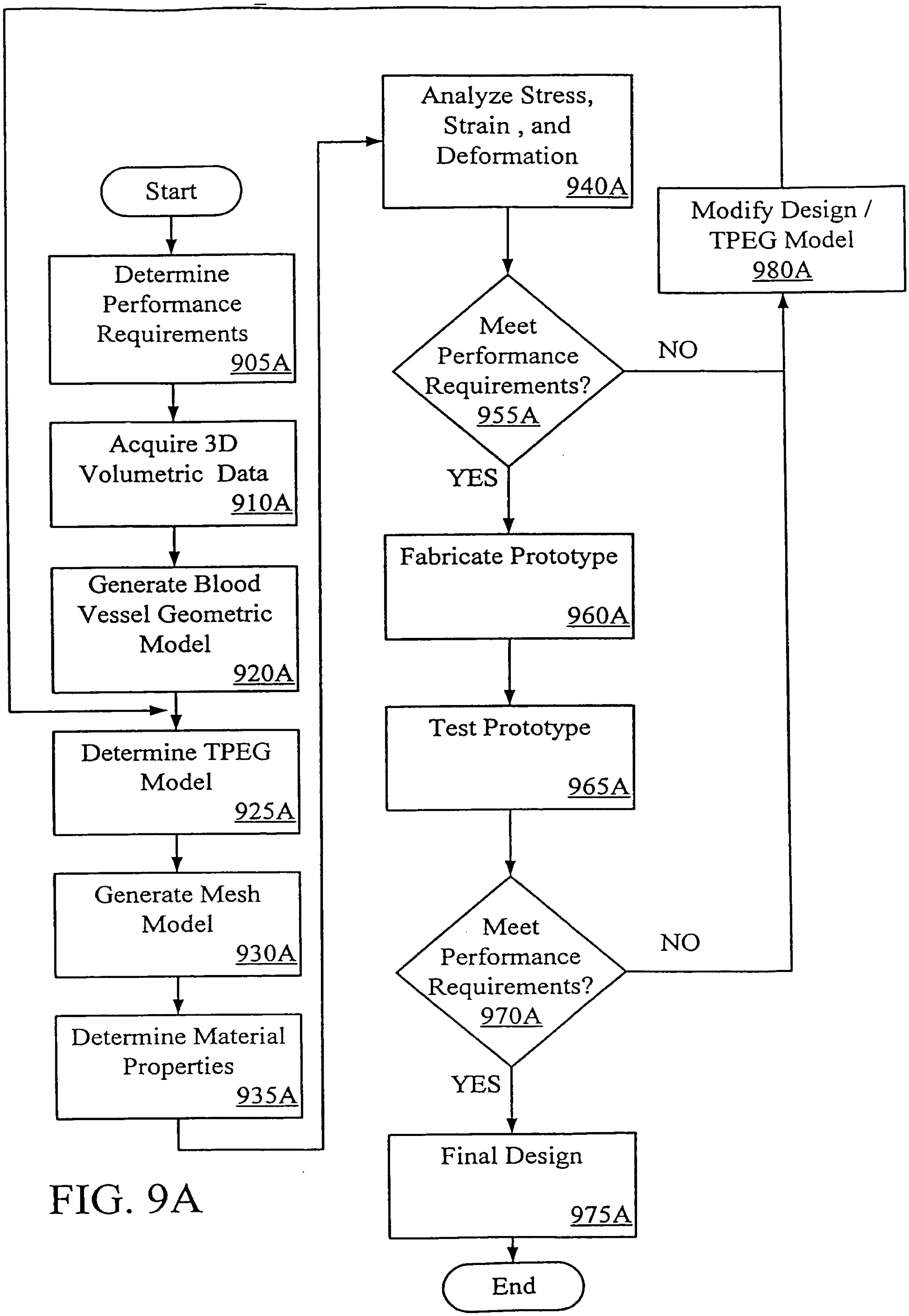
Start
Determine Performance Requirements 905A
Acquire 3D Volumetric Data 910A
Generate Blood Vessel Geometric Model 920A
Determine TPEG Model 925A
Generate Mesh Model 930A
Determine Material Properties 935A
Analyze Stress, Strain , and Deformation 940A
Meet Performance Requirements? 955A
NO
YES
Fabricate Prototype 960A
Test Prototype 965A
Meet Performance Requirements? 970A
NO
YES
Final Design 975A
End
Modify Design / TPEG Model 980A

FIG. 9A

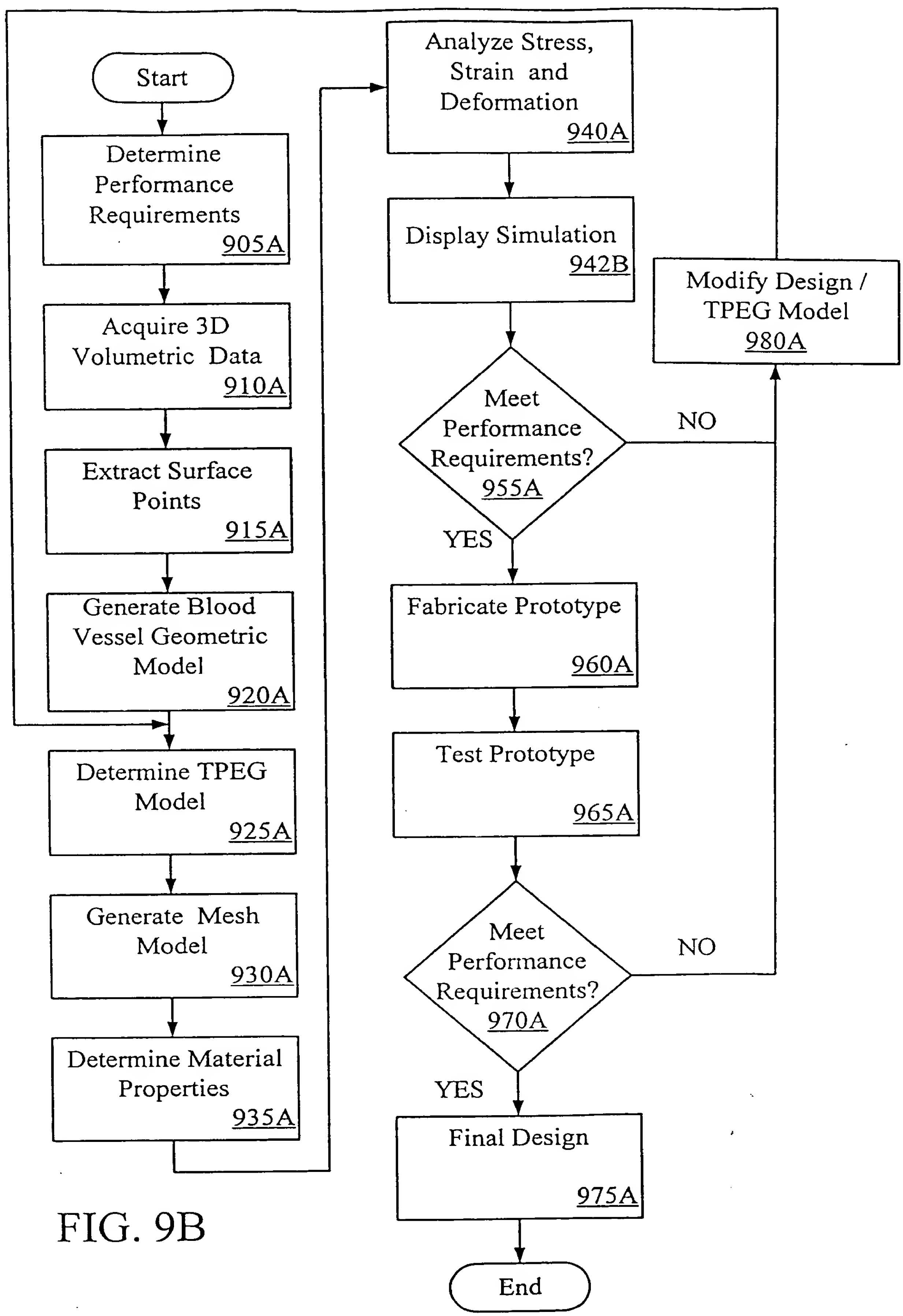
Start
Determine Performance Requirements 905A
Acquire 3D Volumetric Data 910A
Extract Surface Points 915A
Generate Blood Vessel Geometric Model 920A
Determine TPEG Model 925A
Generate Mesh Model 930A
Determine Material Properties 935A
Analyze Stress, Strain and Deformation 940A
Display Simulation 942B
Meet Performance Requirements? 955A
NO
YES
Modify Design / TPEG Model 980A
Fabricate Prototype 960A
Test Prototype 965A
Meet Performance Requirements? 970A
NO
YES
Final Design 975A
End

FIG. 9B

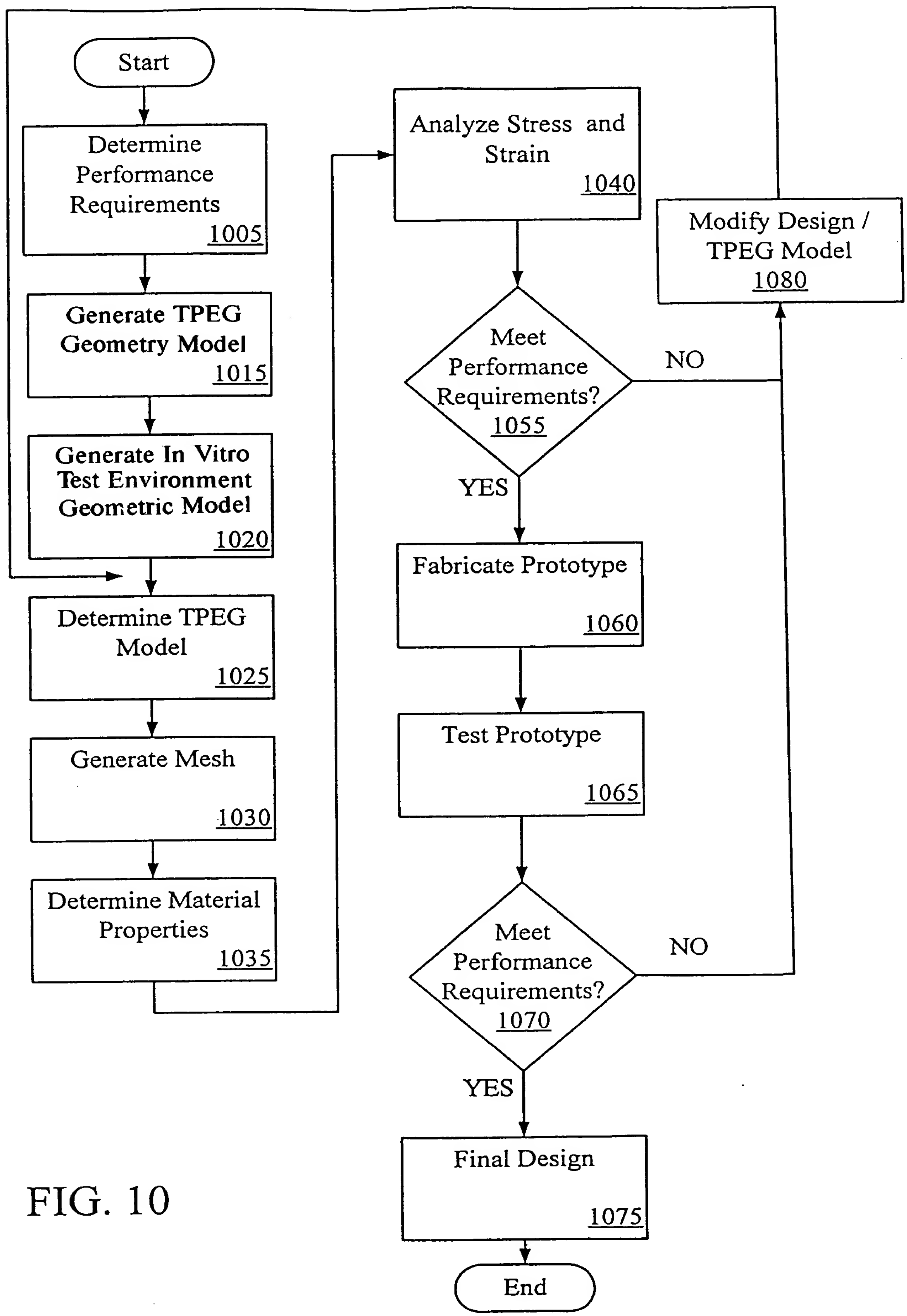
Start
Determine Performance Requirements 1005
Generate TPEG Geometry Model 1015
Generate In Vitro Test Environment Geometric Model 1020
Determine TPEG Model 1025
Generate Mesh 1030
Determine Material Properties 1035
Analyze Stress and Strain 1040
Meet Performance Requirements? 1055
NO
YES
Fabricate Prototype 1060
Test Prototype 1065
Meet Performance Requirements? 1070
NO
YES
Final Design 1075
End
Modify Design / TPEG Model 1080

FIG. 10

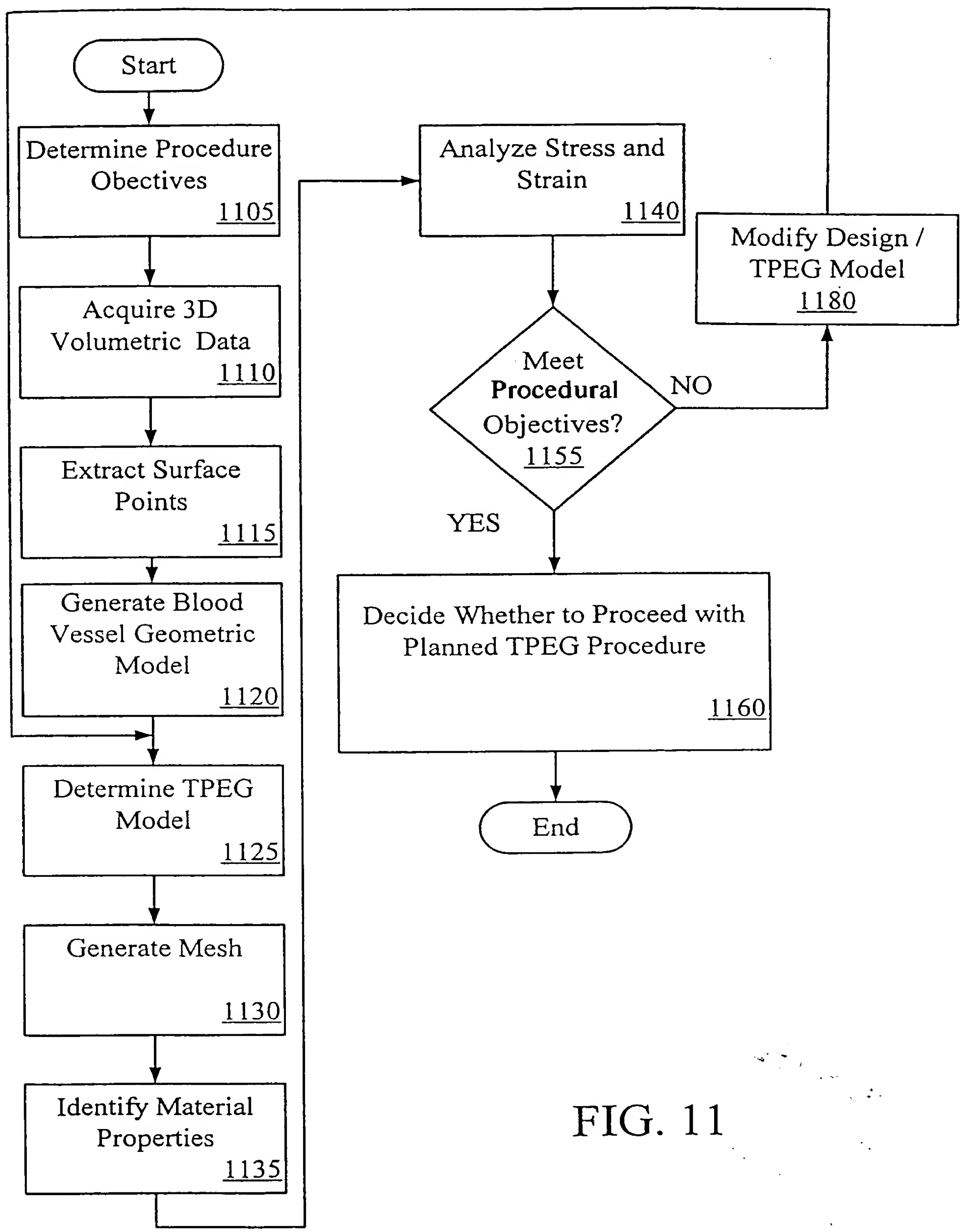
Start
Determine Procedure Obectives 1105
Acquire 3D Volumetric Data 1110
Extract Surface Points 1115
Generate Blood Vessel Geometric Model 1120
Determine TPEG Model 1125
Generate Mesh 1130
Identify Material Properties 1135
Analyze Stress and Strain 1140
Meet Procedural Objectives? 1155
NO
Modify Design / TPEG Model 1180
YES
Decide Whether to Proceed with Planned TPEG Procedure 1160
End

FIG. 11

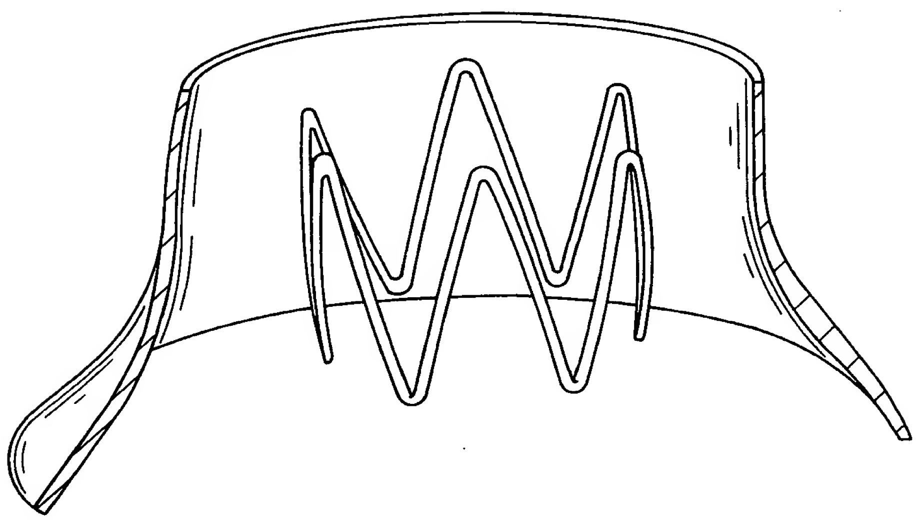

FIG. 12

Title: VIRTUAL PROTOTYPING AND TESTING FOR MEDICAL DEVICE DEVELOPEMENT.
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FIG. 13